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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,301	10/24/2003	Gary K. Schwartz	702-A-US	1477

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EXAMINER	
MARTIN, PAUL C	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,301	SCHWARTZ, GARY K.	
	Examiner	Art Unit	
	Paul C. Martin	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-38,41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-38,41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 31-38, 41 and 42 are pending in this application.

Drawings

Figures 4, 6, 7 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-38 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 36 recites, "the treating of the coptis chinesis extract and the therapeutic agent is performed in a sequential manner." It is unclear whether the coptis chinesis extract is being treated or if the treatment of the subject is performed by administration of the coptis chinesis extract. Claims 37, 38 and 42 are rejected as being dependent on Claim 36.

For purposes of examination, the Examiner has interpreted the claim to mean that treatment of the cancer in a subject is performed by administering an effective amount of coptis chinesis extract and a therapeutic agent sequentially.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li *et al.* (2000).

Li *et al.* teaches a method for inhibiting the cell growth in human cancer cells by administering an effective amount or aqueous chinesis extract (Pg. 1287, Column 2, Lines 10-19 and Pg. 1288, Column 1, Lines 1-7 and Pg. 1289, Fig. 1). Li *et al.* teaches that huanglian is part of a class of novel agents that inhibit tumor growth and suggests the use of huanglian as an oral anticancer drug (Pg. 1293, Column 1, Lines 45, 46 and 54-57).

Li *et al.* teaches that 100% tumor growth inhibition can only be achieved using the whole herbal extract, rather than its individual components, for cancer therapy (Pg. 1293, Column 1, Lines 25-34).

Li *et al.* does not teach wherein the method is used for treating a solid tumor in a subject.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the method of Li *et al.* for inhibiting the cell growth in human cancer cells by administering an effective amount or aqueous chinesis extract as a treatment of a solid tumor in a subject because the herbal extract was shown to inhibit cancer cell growth *in vitro*. One of ordinary skill in the art would have been motivated to use the huanglian extract to treat a solid tumor in a subject in order to determine whether the successful inhibition of cancer cells *in vitro* could be extrapolated to the treatment of cancerous tumor cells *in vivo* in a live subject. There would have been a reasonable expectation of success in adapting the method of Li *et al.* to treating cancer in a subject because Li *et al.* discloses that huanglian extract can inhibit tumor growth and suggests the use of the extract in treating tumor samples from patients.

Claims 31-33, 35-38, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li *et al.* (2000) in view of Lin *et al.* (1999).

The teachings of Li *et al.* were discussed above.

Li *et al.* does not teach a method further comprising a therapeutic agent, a microtubule-destabilizing agent which is a taxol compound, wherein treating cancer of a patient with coptis chinesis extract and a therapeutic agent is performed sequentially, administering the extract first, then the therapeutic agent.

Lin *et al.* teaches administering berberine and paclitaxel (a taxol compound) to human cancer cells, and wherein berberine is a major constituent of Coptis chinesis and is used to inhibit growth in tumor cells (Pg. 416, Column 2, Lines 11-19 and Pg. 420, Fig. 5 D,J,E,K,F,L).

It would have been obvious to combine the method of Li *et al.* for inhibiting the cell growth in human cancer cells by administering an effective amount or aqueous chinesis extract as a treatment of a solid tumor in a subject with the administration of the therapeutic microtubule destabilizing agent paclitaxel in a sequential manner as taught by Lin *et al.* in order to test for a synergistic effect in combining the two inhibitors. One of ordinary skill in the art would have been motivated to combine the two methods in order to examine whether the reduced response seen when combining berberine with paclitaxel would be negated by combining the whole coptis chinesis extract with paclitaxel. There would have been a reasonable expectation of success in combining the two methods because both methods are drawn to the examination of the effects of coptis chinesis components on human cancer cells.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li *et al.* and Lin *et al.* as applied to claims 31-33, 35-38, 41 and 42 above, and further in view of Schwartz *et al.* (US 5,821,072).

Li *et al.* teaches a method for inhibiting the cell growth in human cancer cells by administering an effective amount or aqueous chinesis extract (Pg. 1287, Column 2, Lines 10-19 and Pg. 1288, Column 1, Lines 1-7 and Pg. 1289, Fig. 1). Li *et al.* teaches that huanglian is part of a class of novel agents that inhibit tumor growth and suggests the use of huanglian as an oral anticancer drug (Pg. 1293, Column 1, Lines 45, 46 and 54-57).

Li *et al.* teaches that 100% tumor growth inhibition can only be achieved using the whole herbal extract, rather than its individual components, for cancer therapy (Pg. 1293, Column 1, Lines 25-34).

Li *et al.* does not teach wherein the method is used for treating a solid tumor in a subject.

Li *et al.* does not teach a method further comprising a therapeutic agent, a microtubule-destabilizing agent which is a taxol compound, wherein treating cancer of a patient with coptis chinesis extract and a therapeutic agent is performed sequentially, administering the extract first, then the therapeutic agent.

Li *et al.* does not teach a therapeutic agent comprising a Protein Kinase C (PKC) inhibitor.

Lin *et al.* teaches administering berberine and paclitaxel (a taxol compound) to human cancer cells, and wherein berberine is a major constituent of Coptis chinesis and is used to inhibit growth in tumor cells (Pg. 416, Column 2, Lines 11-19 and Pg. 420, Fig. 5 D,J,E,K,F,L).

Schwartz *et al.* teaches a method of treating cancer in a subject, comprising administering sequentially to the subject an amount of anti-tumor agent paclitaxel followed by an amount of PKC inhibitor (Column 88, Claims 1, 10 and 11).

It would have been obvious to combine the method of Li *et al.* for inhibiting the cell growth in human cancer cells by administering an effective amount or aqueous chinesis extract as a treatment of a solid tumor in a subject with the administration of the therapeutic microtubule destabilizing agent paclitaxel in a sequential manner as taught by Lin *et al.* and the administration of a PKC inhibitor because this would allow one to test for a synergistic effect in combining the three inhibitors greater than that seen in using both or one alone.

One of ordinary skill in the art would have been motivated to combine these three methods in order to determine whether the combination of the three compounds is an effective treatment of cancer in a subject since each compound has been shown to be effective against tumor cells individually. There would have been a reasonable expectation of success in combining the three methods because each is used in methods to treat tumor cells and Coptis chinesis extract, and the taxol component paclitaxel, combined with PKC inhibitors are known in the art as cancer treatments.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one with ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence or evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1655

08/22/06

TERRY MCKELVEY, PH.D.
SUPERVISORY PATENT EXAMINER